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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/125,887	10/05/1998	THIERRY BOON-FALLEUR	EX96002-US	8290

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WILEY, REIN & FIELDING, LLP
ATTN: PATENT ADMINISTRATION
1776 K. STREET N.W.
WASHINGTON, DC 20006

EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 05/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/125,887

Applicant(s)

Boon-Falleur et al.

Examiner

Anne Marie Wehbé

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 10, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-60 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/10/03 has been entered. Claims 20-40 have been canceled. New claims 51-60 have been added. Please note that applicant's after-final amendment which added claims 41-50 was entered on 8/27/02, see the Advisory Action, paper no. 20. Claims 41-60 are pending in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in this action, can be found in previous office actions.

This application still has missing parts. The specification discloses Figures 1-5 and Tables 1-4. While Tables 1-4 are present in the application, Figures 1-5 are missing. Submission of Figures 1-5 is required to complete the application. It is noted that the applicants have stated that

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the omission of Figures 1-5 will be addressed at a later date. However, the applicant has not addressed this issue as yet.

Claim Rejections - 35 USC § 112

The rejection of claims 34-40 under 35 U.S.C. 112, first paragraph, for scope of enablement is withdrawn in view of applicant's cancellation of the claims.

Claim Rejections - 35 USC § 102

The rejection of canceled claims 20-23, 29, and 35-36 under 35 U.S.C. 102(b) over Zhai et al. (1995) Proc. Natl. Acad. Sci., Vol. 36, page 491, abstract 2927, is maintained over claims 41, 44, 46, and 49. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant reiterates the argument put forth in the previous amendments and the after-final amendment that the Zhai abstract lacks sufficient detail to disclose the instant invention and that the reference to MART1 in the abstract does not place the sequence of the tumor-antigen in the hands of the public. The Zhai reference specifically teaches the applicant's invention in that it

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discloses replication recombinant adenoviruses of human serotype Ad2 which encode either the melanoma specific antigens MART-1 or gp100. Prior to the time of filing of the instant application, the sequences of both MART-1 and gp100 were published. In fact, the sequence of MART-1, which is also referred to in the literature as Melan-A/MART-1 or as Melan-A, was published by the instant applicant's in July 1994 in the Journal of Experimental Medicine. Further, the genetic modification of adenoviruses was well known to the skilled artisan at the time of filing and replication defective adenoviruses were available from multiple sources. Thus, the elements of the replication defective recombinant adenoviruses described by Zhai et al. were well known and available at the time of filing. The applicant also reiterates the argument that it is confusing how the Zhai et al. abstract can be considered enabling when applicant's specification is not, since, applicant's opinion, the Zhai et al. reference does not include as much information as the instant specification and that the *in vitro* experiments reported by Zhai et al. do not suggest *in vivo* success. In response to this argument, the advisory action stated that the subject matter of claims 20-33, recombinant adenoviruses, were never rejected under 35 U.S.C. 112, first paragraph, for lack of enablement. Claims 34-40 were rejected based solely on the fact that they encompass *in vivo* methods and therapeutic effects. The previous office actions clearly state that the specification is enabling for *in vitro* methods where the cells expressing the tumor antigen are professional antigen presenting cells. Furthermore, the rejections of record under 35 U.S.C. 102 clearly states that the references have been applied as anticipating the *in vitro* aspects of the invention. The rejection of record does not recite that the Zhai et al. reference teaches *in vivo*

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methods of preparing cytotoxic T cells. Therefore, as Zhai et al. clearly discloses the limitations of the applicant's invention as claimed, Zhai et al. properly anticipates the instant invention.

Claim Rejections - 35 USC § 103

The rejection of claim 30 under 35 U.S.C. 103 over Zhai et al. in view of Haddada et al. is withdrawn in view of applicant's cancellation of the claim.

The rejection of claims 31-33 under 35 U.S.C. 103(a) over Zhai et al. in view of Chen et al. is withdrawn in view of applicant's cancellation of the claims.

The rejection of claims canceled claims 24-28, 37, and 39 over Toso et al. in view of Zhai et al. and Chen et al. is maintained over claims 41-50 and new claims 51-60. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant argues that the Zhai et al. abstract does not enable the production of an adenovirus encoding a tumor-specific antigen. This argument has been addressed in detail above and was not found persuasive. Further, the applicant argues that there is no specific motivation found in the references to arrive at applicant's claims, or even if there was, there was no expectation of success. In response to applicant's argument that there is no suggestion to combine

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the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). It appears that Applicants are arguing that the cited references do not expressly suggest the claimed invention. However, it is well established in case law that a reference must be considered not only for what it expressly teaches, but also for what it fairly suggests. *In re Burkel*, 201 USPQ 67 (CCPA 1979). Furthermore, in the determination of obviousness, the state of the art as well as the level of skill of those in the art are important factors to be considered. The teaching of the cited references must be viewed in light of these factors. It is also noted, that the test for combining references is not what the individual references themselves suggest, but rather what the combination of disclosures taken as a whole would have suggested to one of ordinary skill in the art. *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). For the purpose of combining references, those references need not explicitly suggest combining teachings, much less specific references. *In re Nilssen*, 7 USPQ2d 1500 (Fed. Cir. 1988). Also, in regards to the argument that there is no expectation of success, please note that obviousness does not require absolute predictability of success; for obviousness under 35 U.S.C. § 103, all that is required is a reasonable expectation of success. See *In re O'Farrell*, 7 USPQ2d 1673 (CAFC 1988). The applicant has not provided any reasons why there is no reasonable expectation of success in

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combining the cited references for the reasons presented in previous office actions. Therefore, the rejection of record stands.

No claims are allowed.

This is a continuation of applicant's earlier Application No. 09/125,887. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

